

Calendar No. 372

117TH CONGRESS
2D SESSION

S. 4261

To suspend duties and other restrictions on the importation of infant formula to address the shortage of infant formula in the United States, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MAY 19 (legislative day, MAY 17), 2022

Mr. LEE (for himself, Mr. WICKER, Mr. DAINES, Mr. CASSIDY, and Mr. GRASSLEY) introduced the following bill; which was read the first time

MAY 19, 2022

Read the second time and placed on the calendar

A BILL

To suspend duties and other restrictions on the importation of infant formula to address the shortage of infant formula in the United States, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Fixing Our Regulatory
5 Mayhem Upsetting Little Americans Act” or the “FOR-
6 MULA Act”.

1 **SEC. 2. SUSPENSION OF RESTRICTIONS ON IMPORTATION**
2 **OF INFANT FORMULA TO ADDRESS SHORT-**
3 **AGE.**

4 (a) DUTY-FREE TREATMENT OF INFANT FORMULA
5 IMPORTED FROM CERTAIN COUNTRIES.—

6 (1) IN GENERAL.—During the 180-day period
7 beginning on the date of the enactment of this Act,
8 infant formula described in paragraph (2) shall
9 enter the United States free of duty and free of
10 quantitative limitation.

11 (2) INFANT FORMULA DESCRIBED.—Infant for-
12 mula is described in this paragraph if the infant for-
13 mula—

14 (A) is classified under heading 1901.10 of
15 the Harmonized Tariff Schedule of the United
16 States;

17 (B) is imported from a country described
18 in paragraph (3); and

19 (C) was approved by the agency of the gov-
20 ernment of that country that regulates infant
21 formula.

22 (3) COUNTRIES DESCRIBED.—A country de-
23 scribed in this paragraph is any of the following:

24 (A) Australia.

25 (B) Israel.

26 (C) Japan.

1 (D) New Zealand.

2 (E) Switzerland.

3 (F) South Africa.

4 (G) The United Kingdom.

5 (H) A member country of the European
6 Union.

7 (I) A member country of the European
8 Economic Area.

9 (b) TEMPORARY EXEMPTIONS FROM FDA REQUIRE-
10 MENTS.—

11 (1) IN GENERAL.—With respect to any infant
12 formula introduced or delivered for introduction into
13 interstate commerce pursuant to subsection (a) dur-
14 ing the 180-day period beginning on the date of the
15 enactment of this Act—

16 (A) the requirements under section 412 of
17 the Federal Food, Drug, and Cosmetic Act (21
18 U.S.C. 350a) shall not apply;

19 (B) such infant formula may be manufac-
20 tured, processed, packed, or held in a domestic
21 or foreign facility that is not registered under
22 section 415 of such Act (21 U.S.C. 350d);

23 (C) the requirements under parts 106 and
24 107 of title 21, Code of Federal Regulations,
25 shall not apply; and

1 (D) such infant formula shall not be con-
2 sidered to be misbranded or adulterated solely
3 on the basis of not being in compliance with the
4 requirements of such section 412 or 415, or
5 such part 106 or 107.

6 (2) NOTIFICATION REQUIREMENT.—

7 (A) IN GENERAL.—A person who intro-
8 duces or delivers for introduction into interstate
9 commerce an infant formula pursuant to sub-
10 section (a) shall notify the Secretary of Health
11 and Human Services (referred to in this sub-
12 section as the “Secretary”) if such person has
13 knowledge which reasonably supports the con-
14 clusion that such infant formula—

15 (i) may not provide the nutrients re-
16 quired by section 412(i) of the Federal
17 Food, Drug, and Cosmetic Act (21 U.S.C.
18 350a(i)); or

19 (ii) is a product that meets any cri-
20 terion under section 402(a) of such Act
21 (21 U.S.C. 342(a)), or which otherwise
22 may be unsafe for infant consumption.

23 (B) KNOWLEDGE DEFINED.—For purposes
24 of subparagraph (A), the term “knowledge” as

1 applied to a person subject to such subpara-
2 graph means—

3 (i) the actual knowledge that the man-
4 ufacturer had; or

5 (ii) the knowledge which a reasonable
6 person would have had under like cir-
7 cumstances or which would have been ob-
8 tained upon the exercise of due care.

9 (3) RECALL AUTHORITY.—If the Secretary de-
10 termines that infant formula introduced or delivered
11 for introduction into interstate commerce pursuant
12 to subsection (a) is a product described in paragraph
13 (2)(A)(ii), the manufacturer or importer shall imme-
14 diately take all actions necessary to recall shipments
15 of such infant formula from all wholesale and retail
16 establishments, consistent with recall regulations
17 and guidelines issued by the Secretary.

18 (4) CLARIFICATION.—Section 801(j) of the
19 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
20 381(j)) shall apply with respect to any infant for-
21 mula introduced or delivered for introduction into
22 interstate commerce pursuant to subsection (a) dur-
23 ing the 180-day period beginning on the date of the
24 enactment of this Act.

1 (c) SPECIAL SUPPLEMENTAL NUTRITION PROGRAM
2 FOR WOMEN, INFANTS, AND CHILDREN.—

3 (1) ACCESS FOR WIC BENEFICIARIES.—Not-
4 withstanding any other provision of law, any infant
5 formula introduced or delivered for introduction into
6 interstate commerce pursuant to subsection (a) dur-
7 ing the 180-day period beginning on the date of en-
8 actment of this Act is eligible for purchase using
9 benefits received under the special supplemental nu-
10 trition program for women, infants, and children es-
11 tablished by section 17 of the Child Nutrition Act of
12 1966 (42 U.S.C. 1786).

13 (2) WAIVERS.—

14 (A) DEFINITION OF COVERED DOCU-
15 MENT.—In this paragraph, the term “covered
16 document” means the attachment entitled
17 “Process for State Agency Waiver Requests Re-
18 lated to Shortages” to the letter of the Sec-
19 retary of Agriculture dated February 18, 2022,
20 entitled “Voluntary Recall of Certain Abbott
21 Powder Formulas, including Similac,
22 Alimentum and EleCare”.

23 (B) WAIVERS.—During the 180-day period
24 beginning on the date of enactment of this Act,
25 the Secretary of Agriculture may grant any

1 waiver described in the covered document, in-
2 cluding with respect to the exchange or
3 issuance, as applicable, of infant formula intro-
4 duced or delivered for introduction into inter-
5 state commerce pursuant to subsection (a).

6 (d) LIST OF IMPORTED INFANT FORMULA.—The
7 Secretary of Agriculture, in conjunction with the Secretary
8 of Health and Human Services, shall—

9 (1) maintain a list of all infant formula intro-
10 duced or delivered for introduction into interstate
11 commerce pursuant to subsection (a) during the
12 180-day period beginning on the date of enactment
13 of this Act, which shall include, for each infant for-
14 mula—

15 (A) the country of origin;

16 (B) the recommended measurements for
17 mixing or otherwise preparing the infant for-
18 mula; and

19 (C) the approved use and marketing status
20 of the infant formula in the country of origin
21 according to the applicable government entity
22 that regulates infant formula in that country;
23 and

24 (2) make the list maintained under paragraph

25 (1) publicly available on the websites of each of the

1 Department of Agriculture and the Food and Drug
2 Administration.

3 (e) INFANT FORMULA DEFINED.—In this section,
4 the term “infant formula” has the meaning given that
5 term in section 201(z) of the Federal Food, Drug, and
6 Cosmetic Act (21 U.S.C. 321(z)).

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